

ATTACHMENT C 10/018623

JC07 Rec'd PCT/PTO 18 DEC 2000

Atty Docket No.: 3993.002 Serial No.: _____ Filing Date: _____Applicant: Edward Fritz AND Gerald PhillippsTitle/Mark: RADIATION SOURCE FOR ENDOVASCULAR RADIATION TREATMENT

THE MAIL ROOM STAMP BELOW ACKNOWLEDGES RECEIPT OF THE FOLLOWING DOCUMENTS ON THE DATE INDICATED ON THE MAIL ROOM STAMP.

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| <u>19</u> pg of specification | specimens of the mark |
| <u>4</u> pg of Claims | <input type="checkbox"/> Appl'n for Copyright Registration and _____ |
| <u>2</u> pg of Drawings Informal/Formal | deposits. |
| <u>2</u> pg of Abstract | <input type="checkbox"/> Request for _____ month Extension of Time |
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| <input checked="" type="checkbox"/> Amendment <u>PRELIMINARY</u> | Express Mail No.: <u>FL 568148065US</u> |
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ATTACHMENT D

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Eberhard FRITZ and Gerd PHILLIPPS

Appln. No.: 10/018,623

Group Art Unit: 3736

Filed: December 18, 2001

Examiner: Samuel Gilbert

For: RADIATION SOURCE FOR ENDOVASCULAR RADIATION TREATMENT

Attorney Docket No.: 3993.002

AMENDMENT A

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the Office Action dated November 8, 2002, the period for response being extended by one month to March 8, 2003, by a Petition for a One Month Extension of Time filed herewith, please amend the above-identified application as follows:

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IN THE CLAIMS

23. (Currently amended) A radiation source for use in endovascular radiation treatment, the radiation source comprising: which comprises

at least one ~~or more seeds (treating elements)~~ comprising treating element, wherein each treating element is space apart from the next one, wherein each treating element has a radiation emitting element and means for containment of said radiation emitting element, wherein said [seeds are] at least one treating element is in an elongated container having at least one deflection site,

wherein the at least one deflection site is located in the space between two treating elements.

24. (Previously amended) The radiation source of claim 23, wherein the elongated container is a hollow cylinder.

25. (Previously amended) The radiation source of claim 23, wherein the container is made from a highly flexible material.

26. (Previously amended) The radiation source of claim 25, wherein said flexible material is selected from the group consisting of Ni-Ti-alloy and aluminium alloy

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27. (Previously amended) The radiation source of claim 26, wherein said flexible material is selected from the group consisting of Nitinol and Tinal alloy BB.

28. (Currently amended) A radiation source for use in endovascular radiation treatment, the radiation source comprising:

at least one treating element having a radiation emitting element and means for containment of said radiation emitting element,

wherein said at least one treating element is in an elongated container having at least one deflection site,

~~The radiation source of claim 23, wherein the one or more deflection site(s)~~ at least one deflection site comprises perforation patterns.

29. (Previously amended) The radiation source as in claim 28, wherein said patterns are laser perforations of the container.

30. (Currently amended) A radiation source for use in endovascular radiation treatment, the radiation source comprising:

at least one treating element having a radiation emitting element and means for containment of said radiation emitting element,

wherein said at least one treating element is in an elongated container having at least one deflection site,

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~~The radiation source of claim 23, wherein the~~ at least one deflection site one or more deflection site(s) ~~comprises~~ multiple helical openings in the tube.

31. (Currently amended) The radiation source of claim 23, wherein the ~~seeds~~ at least one treating element comprises rounded or spherical end caps on one or both ends.

32. (Currently amended) The radiation source of claim 23, wherein the ~~seeds are~~ at least one treating element is separated from each other by at least one spacer.

33. (Previously amended) The radiation source of claim 32, wherein said spacer is in form of a sphere.

34. (Currently amended) A radiation source for use in endovascular radiation treatment, the radiation source comprising:

at least one treating element having a radiation emitting element and means for containment of said radiation emitting element,

wherein said at least one treating element is in an elongated container having at least one deflection site,

~~The radiation source of claim 23, wherein the~~ at least one treating element is ~~seeds are~~ spaced from each other and fixed to the inner wall of the container.

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35. (Previously amended) The radiation source of claim 23, wherein said means for containment is a metallic capsule.

36. (Previously amended) The radiation source of claim 23, wherein the radiation emitting element comprises any α -, β - and/or γ -emitting substance.

37. (Previously amended) The radiation source of claim 36, wherein the radiation emitting element comprises one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{186} , W^{188} and I^{135} .

38. (Currently amended) An apparatus for endovascular radiation treatment, the apparatus comprising:

an elongated catheter having a proximal end portion,

a distal end portion and a single first lumen for receiving a radiation source,

optionally a guide wire, and

optionally a second lumen ~~therefore~~, and

a radiation source which comprises ~~one or more seeds~~ (treating elements) at least one treating element, wherein each treating element is space apart from the next one, wherein each treating element has comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said at least one treating element is seeds are in an elongated container having at least one deflection site,

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wherein the at least one deflection site is located in the space between two treating elements.

39. (Previously amended) The apparatus of claim 38, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs¹³⁷, Co⁵⁷, Sr⁸⁹, Y⁹⁰, Au¹⁹⁸, Pd¹⁰³, Se⁷⁵, Sr⁹⁰, Ru¹⁰⁶, P³², Ir¹⁹², Re¹⁸⁸, W¹⁸⁸ and I¹²⁵ contained in a container made from a highly flexible material.

40. (Previously amended) The apparatus of claim 38, further comprising a containment vessel for radiation protection.

41. (Currently amended) An apparatus for endovascular radiation treatment, the apparatus comprising:

an elongated catheter having a proximal end portion,
a distal end portion and a first lumen for receiving a radiation source,

optionally a guide wire,

optionally a second lumen,

a radiation source which comprises at least one treating element comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said at least one treating element is in an elongated container having at least one deflection site, and

~~The apparatus of claim 38, further comprising a magnetic means~~ for guiding the radiation source.

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42. (Previously amended) The apparatus of claim 38, further comprising an x-ray fluoroscopy device.

43. (Currently amended) A method for endovascular radiation treatment comprising the steps of

(a) directing an elongated catheter, having a proximal end portion, a distal end portion and a lumen extending therebetween for receiving a radiation source, to the selected site to be treated preferable by way of a guide wire in a separate lumen;

(b) introducing a radiation source into the catheter at its proximal end portion, which radiation source comprises at least one treating element, wherein each treating element is spaced apart from the next one, one or more seeds (treating elements), wherein said at least one treating element is seeds are in an elongated container having at least one deflection site, wherein the at least one deflection site is located in the space between two treating elements;

(c) moving said radiation source to said distal end portion preferably by way of a transfer wire;

(d) maintaining said radiation source at said distal end portion for a determined period of time; and

(e) retracting said radiation source to the proximal end portion preferably by use of a transfer wire.

44. (Previously amended) The method of claim 43, wherein moving and/or retracting in steps (c) and/or (e) is achieved by pushing or pulling the radiation source.

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45. (Previously amended) The method of claim 43, wherein said movement in step (c) is achieved by pushing and said movement in step (e) is achieved by pulling said radiation source.

46. (Previously amended) The method of claim 43, wherein the radiation source is linked to a transfer wire at its proximal end and moving in step (c) occurs by pushing the transfer wire into the catheter and retracting in step (e) occurs by pulling the transfer wire out of the catheter.

47. (Currently amended) A method for endovascular radiation treatment comprising the steps of

(a) directing an elongated catheter, having a proximal end portion, a distal end portion and a lumen extending therebetween for receiving a radiation source, to the selected site to be treated preferably by way of a guide wire in a separate lumen;

(b) introducing a radiation source into the catheter at its proximal end portion, which radiation source comprises at least one treating element,

wherein said at least one treating element is in an elongated container having at least one deflection site;

(c) moving said radiation source to said distal end portion preferably by way of a transfer wire;

(d) maintaining said radiation source at said distal end portion for a determined period of time; and

(e) retracting said radiation source to the proximal end portion preferably by use of a transfer wire,

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~~The method of claim 43, wherein a radiation source comprising a magnetic elongated container is used and movement in steps (c) and/or (e) is achieved by magnetically pushing and/or pulling the radiation source using a transfer wire comprising a magnet or using an external magnetic means for guiding the radiation source.~~

48. (Previously amended) The method of claim 43, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} contained in a container made from a highly flexible material.

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REMARKS

Review and reconsideration of the Office Action of November 8, 2002, is respectfully requested in view of the above amendment and the following remarks.

Applicants would like to thank the Examiner for the indication that Claims 28-30, 34, 41, and 47 contain allowable subject matter and would be allowable if re-written to overcome the formalities rejections. Claims 28-30, 34, 41, and 47 have been re-written in independent form to overcome the rejection.

Claims have been amended to overcome all the formalities rejections.

Claims 23, 38, and 48 have been amended by adding the limitation that the deflection site is located in the space between two treatment elements (seeds). Support for the claim amendment can be found in Figure 3 and page 14, paragraph 00056, of the specification.

No new matter has been added to the claims.

Applicants would like to point out to the Examiner that compared with independent Claims 23, 38, and 48, the Liprie reference fails to teach that the deflection site is located in the space between two seeds.

In the present invention, the deflection site is located between two treatment elements. With this design, the ends of the treatment elements function as internal joints to support bending of the deflection site(s). Further, the ends allow for

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homogenous three-dimensional distribution of radiation from the treating element so that bending of the radiation-emitting source or the container does not result in inhomogenities of irradiation of the surrounding tissue.

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Office Action

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed 5/30/02.

Applicants thank the Examiner for the indication.

Claim Rejections (Formalities)

The Examiner rejects Claims 23-48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention.

The position of the Examiner can be found on pages 2-3 of the Office Action.

In response, Applicants have amended the claims to overcome the formality rejection.

Accordingly, withdrawal of the rejection is respectfully requested.

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Claim Rejections - Anticipation

The Examiner rejects Claims 23-27, 31, 35-37, 43-46, and 48 under 35 U.S.C. 102(b) as being anticipated by Liprie (5,833,593).

The position of the Examiner can be found on pages 3-4 of the Office Action.

Applicants respectfully traverse.

For a reference to anticipate, it must disclose every single element of the claim.

Compared with independent Claims 23, 38, and 48, the Liprie reference fails to teach that the deflection site is located in the space between two seeds.

In the present invention, the deflection site is located between two treatment elements. With this design, the ends of the treatment elements function as internal joints to support bending of the deflection site(s). Further, the ends allow for homogenous three-dimensional distribution of radiation from the treating element so that bending of the radiation-emitting source or the container does not result in inhomogenities of irradiation of the surrounding tissue.

Applicants reviewed the reference and note that the reference teaches a flexible source wire having a radioactive source that is capable of passing through various conduits in the body. The flexible source wire comprises a flexible housing having a plurality of radioactive cores enclosed in a capsule. See Figure 6 and column 11, lines 14-22. The reference also teaches a deflection point 295. See figures 3a-3d.

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Thus, the reference is not anticipating Claims 23, 38, and 48 of the present invention.

Accordingly, withdrawal of the rejection is respectfully requested.

Claim Rejections - Obviousness

The Examiner rejects Claims 32-33 under 35 U.S.C. 103(a) as being obvious over Liprie (5,833,593).

The position of the Examiner can be found on page 4 of the Office Action

Applicants respectfully traverse for the same reason set forth above and the following remarks:

The claims are novel in view of their dependency with novel claim 23.

The Examiner rejects Claims 38-40 and 42 under 35 U.S.C. 103(a) as being obvious over Liprie (5,833,593).

The position of the Examiner can be found on page 5 of the Office Action.

Applicants respectfully traverse for the same reason set forth above.

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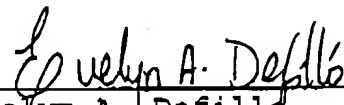
Allowable Subject Matter

The Examiner indicated that Claims 28-30, 34, 41, and 47 contain allowable subject matter and would be allowable if re-written to overcome the formalities rejections.

In response, Applicants have amended the claims in independent form to overcome the formalities rejections.

Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



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Date: March 5, 2003


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CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT A for U.S. Application No. 10/018,623 filed December 18, 2001, were deposited in first class U.S. mail, postage prepaid, Washington, D.C. 20231, on March 5, 2003.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.



Evelyn A. DeFillio